NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DEPOMED, INC.,	:	CIVIL ACTION NO. 13-571 (MLC)(TJB)
Plaintiff,	:	**MEMORANDUM OPINION**
v.	:	
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC. and PURDUE PHARMACEUTICALS L.P.,	:	
Defendants.	:	

Cooper, District Judge

OUTLINE

PRELIMINARY STATEMENT

This is a claim construction opinion in a patent infringement action. The plaintiff, Depomed, Inc. ("Depomed"), has sued defendants Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P. (collectively, "Purdue") for patent infringement pursuant to 35 U.S.C. § 271(a). Depomed alleges that Purdue's controlled-release oxycodone pain-relief drug product, sold under the brand name OxyContin®, infringes claims of U.S. Patent Nos. 6,340,475 ("the '475 Patent") and 6,635,280 ("the '280 Patent") (together, "the patents-in-suit").[1] The patents-in-suit do not claim oxycodone hydrochloride, the active ingredient in OxyContin®, or the treatment of pain. They are directed to compositions and methods for the controlled delivery of a dosage form to the stomach and upper gastrointestinal ("GI") system.

[1] Initially, Depomed also alleged that Purdue's OxyContin® product infringed U.S. Patent Nos. 6,723,340 ("the '340 Patent") and 8,329,215 ("the '215 Patent"). However, the parties subsequently agreed to dismiss, with prejudice, all claims and defenses with respect to the '340 and '215 Patents.

The parties submitted a Joint Claim Construction and Prehearing Statement in which they report agreement as to the meaning of six claim terms common to both patents-in-suit, one claim term exclusive to the '475 Patent, and one claim term exclusive to the '280 Patent. (See dkt. 121-1.)[2] The parties propose constructions for twelve disputed claim terms. (See id.) Seven claim terms are common to both patents-in-suit, two claim terms are exclusive to the '475 Patent, and three claim terms are exclusive to the '280 Patent. The twelve disputed claim terms can be organized into the following six categories: (1) "gastric fluid"; (2) "remains substantially intact"; (3) "until all of said drug is released"; (4) claim terms concerning swelling upon imbibition of water or gastric fluid; (5) claim terms concerning "substantially all of said drug"; and (6) claim terms concerning poly(ethylene oxide) molecular weights. We adopt and utilize these six categories below, when discussing the disputed claim terms.

I. BACKGROUND

A. The asserted '475 and '280 Patents

The '475 Patent and the '280 Patent, both entitled "Extending the Duration of Drug Release Within the Stomach During the Fed Mode," were issued to Depomed as assignee on January 22, 2002 and October 21, 2003, respectively.[3] The '280 Patent is a

[2] The Court will cite to the documents filed on the Electronic Case Filing System ("ECF") by referring to the docket entry numbers by the designation "dkt." Pincites reference ECF pagination.

[3] The '475 Patent is Exhibit 1 to the Amended Complaint. (See dkt. 49-1 at 1-25.) The '280 Patent is Exhibit 2 to the Amended Complaint. (See dkt. 49-1 at 26-51.) Copies of both patents-in-suit are also attached as exhibits to various Markman papers submitted by the parties. We will simply cite those patents by page, drawing sheet, or column and line number.

continuation of the application that issued as the '475 Patent.[4] The patents-in-suit both descend from U.S. Patent Application No. 08/870,509 ("the '509 Application"), filed on June 6, 1997, now abandoned.[5]

The patents-in-suit[6] are directed to compositions and methods for the controlled delivery of a dosage form to the stomach and upper GI system. The Background section explains that conventional drug tablets or capsules can release a drug too quickly when they come into contact with bodily fluids. '475 Pat., col. 1, ll. 30-33. This may result in transient overdoses followed by a long period of underdosing. Id., col. 1, ll. 33-35. Such a delivery pattern is undesirable and of limited clinical usefulness. Id., col 1, ll. 35-36. In addition, drugs in tablet or other dosage forms have a tendency to pass from the stomach into the small intestine after the conclusion of the fed mode[7] with some drug

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[4] The prosecution histories of the patents-in-suit were not supplied to the Court. The parties do not rely on the prosecution histories to support their respective claim construction positions. Thus, a detailed summary of the prosecution histories of the patents-in-suit does not follow.

[5] Purdue did submit excerpts of the prosecution history of the '509 Application. (See dkt. 133-2 at 122-223.)

[6] The '475 and '280 Patents share a common written description. Thus, when describing the contents of the common written description, we cite only the written description of the '475 Patent for convenience. We may also refer to the common written description as only "the written description" for convenience.

[7] The fed mode or postprandial mode is the digestive state. It is distinguishable from the interdigestive state (or fasting mode) by distinct patterns of gastroduodenal motor activity, which determine the gastric retention of the stomach contents. See '475 Pat., col. 11, ll. 23-30. The fed mode may be characterized as follows:

> The postprandial or fed mode is induced by food ingestion, and begins with a rapid and profound change in the motor pattern of the upper GI tract, the change occurring over a period of 30 seconds to one minute. The stomach generates 3-4 continuous and regular

remaining in the tablet or dosage form. Id., col. 2, ll. 17-29. This may result in a loss of effectiveness with drugs that provide their maximum benefit when absorbed in the stomach and upper GI tract. Id., col. 2, ll. 29 – col. 5, ll. 25.

The patents-in-suit address these problems, as well as others, by presenting a "formulation in which the drug is dispersed in a polymeric matrix that is water-swellable rather than merely hydrophilic, that has an erosion rate that is substantially slower than its swelling rate, and that releases the drug primarily by diffusion." Id., col. 5, ll. 58-62. The patents-in-suit explain that "the rate of diffusion of the drug out of the matrix can be slowed by increasing the drug particle size, by the choice of polymer used in the matrix, and/or by the choice of molecular weight of the polymer." Id., col. 5, ll. 63-66. The invention generally operates as follows:

> The matrix . . . swells upon ingestion, preferably to a size that is at least about twice its unswelled volume, and that promotes gastric retention during the fed mode. . . . The penetrating fluid then causes release of the drug in a gradual and prolonged manner by the process of solution diffusion, i.e., dissolution of the drug in the penetrating fluid and diffusion of the dissolved drug back out of the matrix. The matrix itself is solid prior to

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> contractions per minute, similar to those of the interdigestive mode but of about half the amplitude. The change occurs almost simultaneously at all sites of the GI tract, before the stomach contents have reached the distal small intestine. Liquids and small particles flow continuously from the stomach into the small intestine. Contractions of the stomach result in a sieving process that allows liquids and small particles to pass through a partially open pylorus. Indigestible particles greater than the size of the pylorus are retropelled and retained in the stomach. Particles exceeding about 1 cm in size are thus retained in the stomach for approximately 4 to 6 hours.

'475 Pat., col. 11, l. 53 – col. 12, l. 2. A description of the characteristics of the fasting mode is also provided in the written description. See '475 Pat., col. 11, ll. 31-52.

> administration and, once administered, remains undissolved in (i.e., is not eroded by) the gastric fluid for a period of time sufficient to permit the majority of the drug to be released by the solution diffusion process during the fed mode. The rate-limiting factor in the release of the drug is therefore controlled diffusion of the drug from the matrix rather than erosion, dissolving or chemical decomposition of the matrix.
>
> For highly soluble drugs, the swelling of the polymeric matrix thus achieves two objectives—(i) the tablet swells to a size large enough to cause it to be retained in the stomach during the fed mode, and (ii) it retards the rate of diffusion of the highly soluble drug long enough to provide multi-hour, controlled delivery of the drug into the stomach. For drugs that are either sparingly soluble, of limited solubility, or of high solubility, . . . the swelling of the polymeric matrix (i) renders the matrix sufficiently large to cause retention in the stomach during the fed mode, and (ii) localizes the release of the drug to the stomach and small intestine so that the drug will have its full effect without colonic degradation, inactivation, or loss of bioavailability.

Id., col. 5, l. 66 – col. 6, l. 33.

The written description explains that the "water-swellable polymer forming the matrix . . . is any polymer that is non-toxic, that swells in a dimensionally unrestricted manner upon imbibition of water, and that provides for sustained release of an incorporated drug." Id., col. 7, ll. 54-58. Polyalkylene oxides are a class of suitable matrix polymers for use in the invention. See id., col. 7, l. 58 – col. 8, l. 29. Poly(ethylene oxide) is a preferred polyalkylene oxide, according to the written description:

> A particularly preferred polyalkylene oxide is poly(ethylene oxide), which term is used herein to denote a linear polymer of unsubstituted ethylene oxide. Poly(ethylene oxide) polymers having molecular weights of about 4,000,000 and higher are preferred. More preferred are those with molecular weights

> within the range of about 4,500,000 to about 10,000,000, and even more preferred are polymers with molecular weights within the range of about 5,000,000 to about 8,000,000.

Id., col. 8, ll. 31-40. The amount of polymer relative to the drug may vary depending on the desired drug release rate, the polymer itself, the molecular weight of the polymer, and excipients present in the formulation. Id., col. 9, ll. 22-25. However, the polymer must be sufficient to retain a portion of the drug within the matrix one hour after ingestion (or immersion in gastric fluid):

> The amount of polymer will be sufficient however to retain at least about 40% of the drug within the matrix one hour after ingestion (or immersion in the gastric fluid). Preferably, the amount of polymer is such that at least 50% of the drug remains in the matrix one hour after ingestion. More preferably, at least 60%, and most preferably at least 80%, of the drug remains in the matrix one hour after ingestion.

Id., col. 9, ll. 25-32. The drug will be "substantially all released from the matrix within about ten hours, and preferably within about eight hours, after ingestion, and the polymeric matrix will remain substantially intact until all of the drug is released." Id., col. 9, ll. 33-36. The term "substantially intact" is explicitly defined in the written description to mean "a polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles." Id., col. 9, ll. 36-41.

The written description sets forth multiple preferred dosage forms in accordance with the invention. Gelatin capsules containing either two or three pellets of drug impregnated polymer are described in detail by size and shape. See id., col. 10, ll. 20-31. Single, elongated tablets are also described in a similar manner. See id., col. 10, ll. 31-

38. The written description does not provide specific shapes or dimensions that these dosage forms will swell to. The swollen size is generally described in functional terms. See, e.g. id., abstract ("hydrophilic polymers the swell upon imbibition of water to a size that is large enough to promote retention of the dosage form in the stomach during the fed mode"); col. 5, l. 66 – col. 6, l. 3 ("The matrix is a relatively high molecular weight polymer that swells upon ingestion, preferably to a size that is at least about twice its unswelled volume, and that promotes gastric retention during the fed mode"); col. 9, ll. 1-5 ("The hydrophilicity and water swellability of these polymers cause the drug-containing matrices to swell in size in the gastric cavity due to ingress of water in order to achieve a size that will be retained in the stomach when introduced during the fed mode").

The written description also provides multiple examples illustrating the controlled-release behavior of various dosage forms,[8] the sustained release of a dosage form,[9] and differences between subjects in the fed mode and subjects not in the fed mode in terms of gastric retention of tablets of various sizes administered orally.[10]

With respect to the '475 Patent, claims 1, 11-15, 43, and 55 are relevant to this dispute, and are reproduced in the margin.[11] With respect to the '280 Patent, claims 1,

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[8] Example 1 illustrates the controlled-release behavior of metformin hydrochloride from a polymeric matrix consisting of poly(ethylene oxide) in three different dose systems designed to release 90% of their drug contents at approximately 3 hours, 6 hours, or 8 hours. See '475 Pat., col. 12, l. 10 – col. 13, l. 8; Fig. 1. Example 2 illustrates the controlled-release behavior of captopril from a polymeric matrix consisting of poly(ethylene oxide), both with and without glyceryl monostearate. See id., col. 13, ll. 10-38; Fig. 2. Example 3 illustrates the controlled-release behavior of captopril from a polymeric matrix of hydroxyethyl cellulose with the inclusion of glyceryl monostearate at varying pellet sizes. See id., col. 13, ll. 40-63; Fig. 3. Example 4 illustrates the controlled release of metformin hydrochloride, using a higher drug loading, and various polymers and combinations of polymers. See id., col. 13, l. 66 – col. 13, l. 36; Fig. 4. Example 5 illustrates the controlled release of metformin hydrochloride from a single capsule-shaped tablet. See id., col. 14, ll. 39-50; Fig. 5. Example 6 further illustrates the controlled release of captopril, using various polymers and combinations of polymers. See id., col. 14, l. 53 – col. 15, l. 40; Fig. 6. Example 7 presents further data on metformin hydrochloride formulations, illustrating the effect of lower drug loadings than those used in Examples 1, 4, and 5. See id., col. 15, ll. 42-59; Fig. 7. Example 10 further illustrates the controlled release of metformin hydrochloride from a single capsule-shaped tablet. See id., col. 17, ll. 26-37; Fig. 9.

[9] Example 8 illustrates the sustained release of vancomycin hydrochloride from various polymers. See id., col. 15, l. 62 – col. 16, l. 41.

[10] Example 9 illustrates the difference between subjects (both Beagle dogs and humans) in the fed mode and subjects not in the fed mode in terms of the gastric retention of tablets of various sizes administered orally. See id., col. 16, l. 43 – col. 17, l. 23.

[11] **Claim 1**. A controlled-release oral drug dosage form for releasing a drug whose solubility in water is greater than one part by weight of said drug in ten parts by weight of water, said dosage form comprising a solid polymeric matrix with said drug dispersed therein at a weight ratio of drug to polymer of from about 15:85 to about 80:20, **said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode**, that releases said drug into **gastric fluid** by the dissolution and diffusion of said drug out of said matrix by said **gastric fluid**, that

upon immersion in **gastric fluid** retains at least about 40% of said drug one hour after such immersion and **releases substantially all of said drug within about eight hours after such immersion**, and that **remains substantially intact until all of said drug is released**.

Claim 11. A dosage form of claim 1 in which said polymeric matrix is formed of poly(ethylene oxide) at a molecular weight in the range of **about 4,500,000 to about 10,000,000**.

Claim 12. A dosage form of claim 1 in which said polymeric matrix is formed of poly(ethylene oxide) at a molecular weight in the range of **about 5,000,000 to about 8,000,000**.

Claim 13. A dosage form of claim 1 in which said polymeric matrix upon immersion in **gastric fluid** retains at least about 50% of said drug one hour after such immersion.

Claim 14. A dosage form of claim 1 in which said polymeric matrix upon immersion in **gastric fluid** retains at least about 60% of said drug one hour after such immersion.

Claim 15. A dosage form of claim 1 in which said polymeric matrix upon immersion in **gastric fluid** retains at least about 80% of said drug one hour after such immersion.

Claim 43. A method of administering to a subject a drug that is therapeutic to said subject when absorbed in the stomach where said drug has at least one ionized group in the pH range 5 through 8, said method comprising orally administering to said subject a dosage form of said drug while said subject is in a fed mode, said dosage form comprising a solid polymeric matrix with said drug dispersed therein at a weight ratio of drug to polymer of from about 0.01:99.99 to about 80:20, **said polymeric matrix being one that:**

(a) **swells upon imbibition of gastric fluid to a size large enough to promote retention in the stomach during said fed mode**,
(b) releases said drug into **gastric fluid** by the dissolving of said drug by said **gastric fluid** and either erosion of said matrix or diffusion of said dissolved drug out of said matrix,
(c) retains at least about 40% of said drug one hour after such immersion in **gastric fluid**,
(d) **releases substantially all of said drug within about ten hours after such immersion**, and
(e) **remains substantially intact until all of said drug is released**,

thereby extending the release rate of said drug with time during said fed mode **while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic environment**.

Claim 55. A method in accordance with claim 43, in which said solid polymeric matrix comprises poly(ethylene oxide) at a molecular weight of from **about 4,500,000 to about 10,000,000**.

‘475 Pat., col. 17, ll. 45-59; col. 18, ll. 21-35; col. 25, ll. 39-64 (emphasis added).

11-15, 43, and 45-46 are relevant to this dispute, and are also reproduced in the margin.[12] The disputed claim terms are bolded and will be discussed in more detail in Section I.B, infra.

[12] **Claim 1**. A controlled-release oral drug dosage form for releasing a drug whose solubility in water is greater than one part by weight of said drug in ten parts by weight of water, said dosage form comprising one or more polymers forming a solid polymeric matrix with said drug incorporated therein at a weight ratio of drug to polymer of from 15:85 to 80:20, said dosage form being one that **when swollen in a dimensionally unrestricted manner as a result of imbibition of water is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode**, that releases said drug into **gastric fluid** by the dissolution and diffusion of said drug out of said matrix by said **gastric fluid**, that upon immersion in **gastric fluid** retains at least about 40% of said drug one hour after such immersion and **releases substantially all of said drug after such immersion**, and that **remains substantially intact until substantially all of said drug is released**.

Claim 11. A dosage form in accordance with claim 1 in which said polymeric matrix is formed of poly(ethylene oxide) at a molecular weight in the range of **about 4,500,000 to about 10,000,000**.

Claim 12. A dosage form in accordance with claim 1 in which said polymeric matrix is formed of poly(ethylene oxide) at a molecular weight in the range of **about 5,000,000 to about 8,000,000**.

Claim 13. A dosage form in accordance with claim 1 in which said polymeric matrix upon immersion in **gastric fluid** retains at least about 50% of said drug one hour after such immersion.

Claim 14. A dosage form in accordance with claim 1 in which said polymeric matrix upon immersion in **gastric fluid** retains at least about 60% of said drug one hour after such immersion.

Claim 15. A dosage form in accordance with claim 1 in which said polymeric matrix upon immersion in **gastric fluid** retains at least about 80% of said drug one hour after such immersion.

Claim 43. A method of administering to a subject a drug that is therapeutic to said subject when absorbed in the stomach where said drug has at least one ionized group in the pH range 5 through 8, said method comprising orally administering to said subject a dosage form of said drug while said subject is in a fed mode, said dosage form comprising one or more polymers forming a solid polymeric matrix with said drug incorporated therein at a weight ratio of drug to polymer of from 0.01:99.99 to 80:20, said polymeric matrix being one that:

B. The disputed claim terms

As discussed above, there are twelve claim terms in dispute. These terms are organized into six categories: (1) "gastric fluid"; (2) "remains substantially intact"; (3) "until all of said drug is released"; (4) claim terms concerning swelling upon imbibition of water or gastric fluid; (5) claim terms concerning "substantially all of said drug"; and (6) claim terms concerning poly(ethylene oxide) molecular weights. This section summarizes the parties' proposed constructions for the claim terms in dispute. This section also provides, when applicable, a brief summary of the claim construction history for these terms. Many of the terms at issue here were previously construed by multiple district courts and the Patent Trials and Appeal Board ("PTAB").

(a) **when swollen in a dimensionally unrestricted manner as a result of imbibition of gastric fluid is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode**,
(b) releases said drug into **gastric fluid** by the dissolving of said drug by said **gastric fluid** and either erosion of said matrix or diffusion of said dissolved drug out of said matrix,
(c) protects any unreleased drug in said matrix from said **gastric fluid**,
(d) retains at least about 40% of said drug one hour after such immersion in **gastric fluid**, and
(e) **releases substantially all of said drug within about ten hours after such immersion**,

thereby extending the release rate of said drug with time during said fed mode **while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic environment**.

Claim 45. A dosage form in accordance with claim 1 in which said dosage form **releases substantially all of said drug within about ten hours after immersion** in **gastric fluid**.

Claim 46. A dosage form in accordance with claim 1 in which said dosage form **releases substantially all of said drug within about eight hours after immersion** in **gastric fluid**.

'280 Pat., col. 17, ll. 45-61; col. 18, ll. 24-43; col. 25, ll. 36-62; col. 26, ll. 24-29 (emphasis added).

1. "Gastric fluid"

The claim term "gastric fluid" appears in claims 1, 13-15, and 43 of the '475 Patent and claims 1, 13-15, 43, 45, and 46 of the '280 Patent. See nn. 8, 9, supra. The parties' respective constructions are as follows:

Term Identified for Construction	Depomed's Proposed Construction	Purdue's Proposed Construction
"gastric fluid"	"both the fluid in the stomach and simulated or artificial fluids recognized by those skill[ed] in the art as a suitable model for the fluid of the human stomach"	"Encompasses both fluid in the human stomach, and any simulated or artificial fluids recognized by those skilled in the art as a suitable model for the fluid of the human stomach."

(Dkt. 121-1 at 13-15.) The dispute between the parties is whether the term "gastric fluid" is limited to mean only fluid in the **human** stomach. This claim term has been construed by three district courts and in three *inter partes* review ("IPR") proceedings.[13]

In Depomed, Inc. v. Ivax Corp., No. C 06-00100, 2006 WL 3782829 (N.D. Cal. December 20, 2006) (hereinafter "Ivax"), Judge Charles R. Breyer concluded that the term "gastric fluid" was "entitled to a broad construction that encompasses both the fluid in the human stomach, and any simulated or artificial fluids recognized by those skilled in the art as a suitable model for the fluid of the human stomach." Id. at *8. The two

[13] The PTAB may construe patent claims during an IPR proceeding. The PTAB interprets claim terms in an unexpired patent according to their broadest reasonable construction, in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); In re Cuozzo Speed Techs., LLC, 793 F.3d 1268, 1275-79 (Fed. Cir. 2015), aff'd sub nom. Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131 (2016). The PTAB's constructions are not binding on this Court.

other district courts construed the term to mean "both the fluid in the stomach and simulated or artificial fluids recognized by those skilled in the art as a suitable model for the fluid of the human stomach." See Depomed, Inc. v. Sun Pharma Global FZE, No. 11-3553, 2012 WL 3201962 (D.N.J Aug. 3, 2012) (hereinafter "Sun")[14]; Depomed, Inc. v. Lupin Pharmaceuticals, Inc., No. C 09-5587, 2011 WL 1877984, at *9 (N.D. Cal. May 17, 2011) (hereinafter "Lupin"). In all three of the IPR proceedings, the parties agreed to apply the construction from the Sun and Lupin cases. (See dkt. 132-9; dkt. 132-10; dkt. 132-11; dkt. 132-12; dkt. 132-13; dkt. 132-14.)

2. "Remains substantially intact"

The claim term "remains substantially intact" appears in claims 1 and 43 of the '475 Patent and claim 1 of the '280 Patent. See nn. 8, 9, supra. The parties' respective constructions are as follows:

Term Identified for Construction	Depomed's Proposed Construction	Purdue's Proposed Construction
"remains substantially intact"	"A polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles"	"A polymeric matrix in which the swollen polymer substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles"

[14] In Sun, the court noted that the parties agreed on the term "gastric fluid," and therefore no further construction was necessary. Sun, 2012 WL 3201962, at *9. The Sun Court's Order construing the term "gastric fluid" may be found at Depomed, Inc. v. Sun Pharma Global FZE, No. 11-3553, 2012 WL 9514228, at *1 (D.N.J. Aug. 3, 2012).

(Dkt. 121-1 at 26-27.) The dispute between the parties is whether the "substantial intactness" is limited to a specific portion of the matrix. This claim term has been construed by two district courts and in three IPR proceedings. The construction adopted by the court in Lupin, which was agreed to by the parties in that case, is identical to the construction proposed by Depomed here. See Lupin, 2011 WL 1877984, at *16. Judge Pisano's construction in Depomed, Inc. v. Actavis Elizabeth LLC, Nos. 12-1358, 12-2813, 2014 WL 316702 (D.N.J. Jan. 28, 2014) (hereinafter "Actavis"), is also identical to Depomed's proposed construction. See id. at *10. In the IPR proceedings, Purdue did not propose a construction for this claim term. In all three proceedings, the PTAB adopted Depomed's proposed construction, which is identical to the one proposed here. (See dkt. 132-9, dkt. 132-10, dkt. 132-11, dkt. 132-12, dkt. 132-13, dkt. 132-14.)

3. "Until all of said drug is released"

The claim term "until all of said drug is released" appears in claims 1 and 43 of the '475 Patent. See n. 8, supra. The parties' respective constructions are as follows:

Term Identified for Construction	Depomed's Proposed Construction	Purdue's Proposed Construction
"until all of said drug is released"	"until the plateau of the dissolution profile characterizing drug release from the swollen dosage form is reached"	"100% of the drug has been released"

(Dkt. 121-1 at 24-26.) The dispute between the parties is over the amount of drug that must be released to constitute "all" of the drug being released. This claim term has been construed by two district courts and in two IPR proceedings. In Sun and Lupin, this claim term was construed to mean "until the plateau of the dissolution profile

characterizing drug release from the swollen dosage form is reached," the same construction Depomed advocates for here. See Sun, 2012 WL 3201962, at *12; Lupin, 2011 WL 1877984, at *11-13. However, in two of the IPR proceedings between the parties, the PTAB rejected the construction Depomed proposes here, and instead construed the term to have its plain, ordinary meaning. (See dkt. 132-12 at 8-10; dkt. 132-14 at 8-10.)

4. Claim terms concerning swelling upon imbibition of water or gastric fluid

The following claim terms concern the swelling of the dosage form upon imbibition of water or gastric fluid. The claim term "said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode" appears in claim 1 of the '475 Patent. See n. 8, supra. The claim term "said polymeric matrix being one that swells upon imbibition of gastric fluid to a size large enough to promote retention in the stomach during said fed mode" appears in claim 43 of the '475 Patent. See id. These claim terms are very similar, and the parties each propose a single construction for both terms. These terms differ with respect to the type of imbibition fluid (i.e., water vs. gastric fluid) and some additional minor language. The parties' respective constructions are as follows:

Term Identified for Construction	Depomed's Proposed Construction	Purdue's Proposed Construction
"said polymeric matrix being one the swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode" "said polymeric matrix being one that swells upon imbibition of gastric fluid to a size large enough to promote retention in the stomach during said fed mode"	"the dosage form, which comprises a polymeric matrix, increases in size due to the ingress of [water/gastric fluid], such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours"	"The polymeric matrix of the oral drug dosage form increases in size upon imbibition of water to a size exceeding 9.5 mm diameter x 9.5 mm length, such that when the dosage form is introduced into the stomach during the fed mode, it remains in the stomach for at least 4 hours"

(Dkt. 121-1 at 9-11.)

The claim term "when swollen in a dimensionally unrestricted manner as a result of imbibition of [water/gastric fluid] is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode" appears in claims 1 and 43 of the '280 Patent.[15] See n. 9, supra. The parties' respective constructions are as follows:

[15] Claim 1 of the '280 Patent recites "imbibition of water," and claim 43 of the '280 patent recites "imbibition of gastric fluid."

Term Identified for Construction	Depomed's Proposed Construction	Purdue's Proposed Construction
"when swollen in a dimensionally unrestricted manner as a result of imbibition of [water/gastric fluid] is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode"	"'when swollen in a dimensionally unrestricted manner as a result of imbibition of [water/gastric fluid]' is given its plain and ordinary meaning" "'is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode' means 'such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours"	"The dosage form, which comprises a polymeric matrix, increases in size upon imbibition of [water/gastric fluid] to a size exceeding 9.5 mm diameter x 9.5 mm length, such that when the dosage form is introduced into the stomach during the fed mode, it remains in the stomach for at least 4 hours"

(Dkt. 121-1 at 11-13.)

In Lupin, Judge Hamilton construed the terms "said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode" and "said dosage form being one that when swollen in a dimensionally unrestricted manner as a result of imbibition of water is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during the fed mode" together to mean "the dosage form, which comprises a polymeric matrix, increases in size due to the ingress of water, such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours." Lupin, 2011 WL 1877984, at *5-9. The dispute in the Lupin case regarding these claim terms involved whether the polymeric matrix swells in an "unrestricted" manner, and whether the polymeric matrix remains "solid" when it swells.

See id., at *6. Those disputes are different than the disputes we are asked to address, i.e., limitations as to the size of the swollen matrix and the time the dosage form remains in the stomach.[16]

The Court in Sun adopted an identical construction for these terms, noting that the parties agreed to Judge Hamilton's construction from Lupin during their Markman hearing. See Sun, 2012 WL 3201962, at *8.

In Ivax, Judge Breyer construed the terms "said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode" and "said dosage form being one that when swollen in a dimensionally unrestricted manner as a result of imbibition of water is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during the fed mode" together to mean that "the drug dosage form's polymeric matrix increases in size, and does not erode, such that when introduced to a stomach in the fed mode, the dosage form remains in the stomach for several hours." Ivax, 2006 WL 3782829, at *14. Judge Breyer articulated the "crucial question" to be "how large the swollen dosage form must be in order to 'promote retention.'" Id. at *12. Depomed proposed that a swollen size of 8 mm would be appropriate. Id. at *13. Ivax argued that a numeric boundary was not required, but offered a range between 2 mm to 20 mm, if one must be determined. Id. at *12. Judge Breyer declined to impose a minimum size of

[16] The Court notes that in Lupin, Lupin originally proposed a size limitation for the swollen matrix of "at least 20% greater than that of the starting tablet," but withdrew that limitation in a responsive brief. See Lupin, 2011 WL 1877984, at *5.

the swollen dosage form necessary to promote retention, because there was an "absence of compelling intrinsic or extrinsic evidence indicating that a specific size would be sufficient to promote retention." Id. at *13. The Court reasoned that:

> A patentee has the right to claim the invention in terms that would be understood by persons of skill in the art, and "mathematical precision should not be imposed for its own sake." [Modine Mfg. Co. v. U.S. Intern. Trade Comm'n, 75 F.3d 1545, 1557 (Fed. Cir. 1996)]. A person of skill in the art reading the patent as a whole would recognize that the claimed polymer matrices must swell upon absorption of water, and must not significantly erode throughout the relevant period of immersion in gastric fluid. Moreover, a person of skill in the art would recognize that the patent discloses that a tablet of a given composition and of 4 mm in size would perform as claimed—that is, such a dosage form attained a size that is "large enough to promote retention" in the subjects that were studied. See '475 patent at 17:9–24. From this basic teaching, one of skill in art would understand both the requirements and the means for testing for compliance with the claim requirements. The Court declines to impose a more specific construction of the disputed claim terms, especially since tying the scope of the disputed claim to a minimum size that is supported primarily by the result from one example would impermissibly read a limitation into the claims.

Id.

In Actavis, Judge Pisano construed the term "thereby attaining a size large enough to promote retention in the stomach during said fed mode" and "is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode" together to mean "such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours." Actavis, 2014 WL 316702, at *3-5. In Actavis, neither party advocated for a construction that included a size limitation. In that case, the dispute focused on the duration of the

retention of the dosage form in the stomach. Depomed's proposed construction was "temporal," requiring the drug to remain in the stomach for "several hours." Actavis' proposed construction was "functional," requiring the dosage form to remain in the stomach until the entirety of the drug is delivered. See id. at *4. Judge Pisano adopted Depomed's construction, relying on the discussion of drug retention in terms of time, not drug delivery. See id. at *5. Judge Pisano did not, and was not asked to, define a specific amount of time, as the parties ask us to do here. Judge Pisano also declined to construe the term "said dosage form being one that when swollen in a dimensionally unrestricted manner as a result of imbibition of water." See id. at *8-9. He rejected "any limitation on the rate or extent of swelling, so long as there is swelling of the dimension of the dosage form" and found that the term's plain and ordinary meaning should apply. Id. at *8-9.

5. Claim terms concerning "substantially all of said drug"

The following five claim terms concern the release of "substantially all of said drug" from the dosage form. For each of these claim terms, Purdue does not propose a construction, and instead contends that they are indefinite. (See dkt. 133 at 16-27; dkt. 159 at 12-22.)

The claim term "releases substantially all of said drug within about eight hours after such immersion" appears in claim 1 of the '475 Patent and claim 46 of the '280 Patent. See nn. 8, 9, supra. Depomed's proposed construction is as follows:

Term Identified for Construction	Depomed's Proposed Construction
"releases substantially all of said drug within about eight hours after such immersion"	"at least 80% of the drug has been released after eight hours of immersion in gastric fluid"

(Dkt. 121-1 at 15-17.)

The claim term "releases substantially all of said drug after such immersion" appears in claim 1 of the '280 Patent. See n. 9, supra. Depomed's proposed construction is as follows:

Term Identified for Construction	Depomed's Proposed Construction
"releases substantially all of said drug after such immersion"	"at least 80% of the drug has been released after immersion in gastric fluid"

(Dkt. 121-1 at 17-18.)

The claim term "releases substantially all of said drug within about ten hours after such immersion" appears in claim 43 of the '475 Patent and claims 43 and 45 of the '280 Patent. See nn. 8, 9, supra. Depomed's proposed construction is as follows:

Term Identified for Construction	Depomed's Proposed Construction
"releases substantially all of said drug within about ten hours after such immersion"	"at least 80% of the drug has been released after ten hours of immersion in gastric fluid"

(Dkt. 121-1 at 19-20.)

The claim term "until substantially all of said drug is released" appears in claim 1 of the '280 Patent. See n. 9, supra. Depomed's proposed construction is as follows:

Term Identified for Construction	Depomed's Proposed Construction
"until substantially all of said drug is released"	"at least 80% of the drug has been released"

(Dkt. 121-1 at 20-22.)

The claim term "while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic environment" appears in claim 43 of the '475 Patent and claim 43 of the '280 Patent. See nn. 8, 9, supra. Depomed's proposed construction is as follows:

Term Identified for Construction	Depomed's Proposed Construction
"while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic environment"	"at least 80% of the drug has been released after immersion in gastric fluid"

(Dkt. 121-1 at 22-24.)

The five claim terms identified above, or portions thereof, have been construed by three district courts and in multiple IPR proceedings. The district courts that have been asked to construe these terms have consistently construed the phrase "substantially all of said drug" to mean "at least 80% of the drug." See Sun, 2012 WL 3201962, at *9-11 (construing the terms "releases substantially all of said drug within about eight hours after such immersion," "until substantially all of said drug is released," and "while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic environment" to mean "at least 80% of the drug has been released after eight hours of immersion in gastric fluid"); Lupin, 2011 WL 1877984, at *11 (construing

"releases substantially all of said drug within about eight hours after such immersion" to mean "at least 80% of the drug has been released after eight hours of immersion in gastric fluid" and "until substantially all of said drug is released" means "at least 80% of the drug has been released after eight hours of immersion in gastric fluid" per the parties' agreement); Ivax, 2006 WL 3782829, at *4-5 (construing the term "releases substantially all of said drug within about eight hours after such immersion" to mean that "at least 80% of the drug has been released after eight hours"). The PTAB has also adopted similar, if not identical, constructions. (See dkt. 132-9, dkt. 132-10, dkt. 132-11, dkt. 132-12, dkt. 132-13, dkt. 132-14.)

6. Claim terms concerning poly(ethylene oxide) molecular weights

The following two claim terms concern the molecular weight of the poly(ethylene oxide) used to form the polymeric matrix.

The claim term "about 4,500,000 to about 10,000,000" appears in claims 11 and 55 of the '475 Patent and claim 11 of the '280 Patent. See nn. 8, 9, supra. The parties' respective constructions are as follows:

Term Identified for Construction	Depomed's Proposed Construction	Purdue's Proposed Construction
"about 4,500,000 to about 10,000,000"	"Plain and ordinary meaning"	"4,275,000 to 10,500,000"

(Dkt. 121-1 at 28.)

The claim term "about 5,000,000 to about 8,000,000" appears in claim 12 of the '475 Patent and claim 12 of the '280 Patent. See nn. 8, 9, supra. The parties' respective constructions are as follows:

Term Identified for Construction	Depomed's Proposed Construction	Purdue's Proposed Construction
"about 5,000,000 to about 8,000,000"	"Plain and ordinary meaning"	"4,750,000 to 8,400,000"

(Dkt. 121-1 at 28-29.)

As far as the Court is aware, these claim terms have not previously been the subject of claim construction.

II. DISCUSSION

A. Legal standard

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Claim construction determines the correct claim scope, and is a determination exclusively for the court as a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 978-79 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). The focus in construing disputed terms in claim language "is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term[s] to mean." Id. at 986.

To determine the meaning of the claims, courts start by considering the intrinsic evidence. Phillips, 415 F.3d at 1313; C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 861 (Fed. Cir. 2004); Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc., 262 F.3d 1258, 1267 (Fed. Cir. 2001). The intrinsic evidence includes the claims

themselves, the specification, and the prosecution history. Phillips, 415 F.3d at 1314; C.R. Bard, Inc., 388 F.3d at 861.

The claims themselves provide substantial guidance in determining the meaning of particular claim terms. Phillips, 415 F.3d at 1314. First, the context in which a term is used in the asserted claim can be very instructive. Id. Other asserted or unasserted claims can aid in determining the claim's meaning because claim terms are normally used consistently throughout a patent. Id. Differences among claims can also assist in understanding a term's meaning. Id. For example, when a dependent claim adds a limitation, there is a presumption that the independent claim does not include that limitation. Id. at 1314-15.

"[C]laims 'must be read in view of the specification of which they are a part.'" Id. at 1315 (quoting Markman, 52 F.3d at 979). "[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" Id. (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). This is true because a patentee may define his own terms, give a claim term a different meaning than the term would otherwise possess, or disclaim or disavow the claim scope. Id. at 1316. In these circumstances, the inventor's lexicography governs. Id. The specification may also resolve the meaning of ambiguous claim terms "where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed. Cir. 2002). But, "[a]lthough the specification may aid the court in interpreting the meaning of

disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims." Comark Commc'ns, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998) (quoting Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed. Cir. 1988)); accord Phillips, 415 F.3d at 1323.

The prosecution history is another tool to supply the proper context for claim construction. It "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower that it would otherwise be." Phillips, 415 F.3d at 1317.

"Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Markman, 52 F.3d at 980. Although extrinsic evidence can be useful, it is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" Phillips, 415 F.3d at 1317 (quoting C.R. Bard, Inc., 388 F.3d at 862).

Dictionaries and treatises may aid a court in understanding the underlying technology and the manner in which one skilled in the art might use claim terms, but dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. Id. at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert's conclusory, unsupported assertions as to a term's definition are entirely unhelpful to a court. Id.

Generally, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms." Id. The Supreme Court recently explained the role of extrinsic evidence in claim construction:

> In some cases, however, the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period. . . . In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the "evidentiary underpinnings" of claim construction that we discussed in Markman, and this subsidiary factfinding must be reviewed for clear error on appeal.

Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

As is sometimes the case, the claim terms requiring construction may have been the subject of prior claim construction proceedings by other district courts, or even the same court. While rulings of the Federal Circuit on issues of claim construction for a given patent are binding on later district courts analyzing the same patent, interpretations of the same or other district courts of the same terms in the patent or patent family are generally not binding. See Shire Dev. LLC v. Amneal Pharms. LLC, Civ. No. 15-2865, 2016 WL 4119940, at *2 (D.N.J. Aug. 2, 2016); see also Ravo v. Tyco Healthcare Group LP, Civ. No. 11-1637, 2013 WL 3326657, at *6 (W.D. Pa. Mar. 13, 2013). However, the interpretations of the same or other district courts are generally considered to be highly relevant and persuasive authority. Shire, 2016 WL 4119940, at *2.

Overall, in construing the claims, "[t]he judge's task is not to decide which of the adversaries is correct. Instead, the judge must independently assess the claims, the

specification, and if necessary the prosecution history and relevant extrinsic evidence, and declare the meaning of the claims." Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1556 (Fed. Cir. 1995).

B. Definition of the person of ordinary skill in the art

The parties' experts, Dr. Leah Appel, Ph.D. (Depomed) and Dr. Jerry L. Atwood, Ph.D. (Purdue), are well regarded and highly qualified to opine on the matters they did. The proposed definitions for the person of ordinary skill in the art ("POSA") offered by the parties differ slightly.[17] The second portion of Depomed's definition includes the definition set forth by Purdue. Neither party has lodged an objection with respect to these definitions. Accordingly, the Court will adopt Depomed's definition:

> a person of ordinary skill in the art would have at least a bachelor's degree in the fields of chemistry, chemical engineering, pharmaceutical science and/or material science with a focus on polymer science, combined with substantial experience in development of controlled release drug dosage forms (even more desirably oral controlled release dosage forms). Alternatively, if the person had obtained a Ph.D. in any of the relevant fields, the required amount of industry experience would decline to about two years.

(Dkt. 132-17 at 4.)

[17] Dr. Appel defines the POSA as an individual having "at least a bachelor's degree in the fields of chemistry, chemical engineering, pharmaceutical science and/or material science with a focus on polymer science, combined with substantial experience in development of controlled release drug dosage forms (even more desirably oral controlled release dosage forms)." (Dkt. 132-17 at 4.) Dr. Appel also states, in the alternative, that "if the person had obtained a Ph.D. in any of the relevant fields, the required amount of industry experience would decline to about two years." (Id.)

Dr. Atwood defines the POSA as an individual having "a Ph.D. degree in pharmaceutics, chemistry or chemical engineering, along with at least two years of industrial experience in the development of controlled-release oral dosage forms." (Dkt. 133-1 at 4.)

C. Application

We address the disputed claim terms according to the six categories discussed above. We have reviewed the written submissions of the parties, and conducted a one-day claim construction hearing. (See dkt. 247, Markman Hr'g Tr.) The written submissions of the parties with respect to the disputed claim terms are listed in the margin.[18]

1. "Gastric fluid"

For this claim term, each party adopts the construction reached in a previous claim construction proceeding. See Section I.B.1, supra. Depomed adopts the construction from both the Sun and Lupin cases verbatim. Purdue adopts the construction from the Ivax case, removing only Judge Breyer's preamble language that notes this term is "entitled to a broad construction." The difference between the parties' constructions is that Depomed's construction of "gastric fluid" includes fluid from non-human animal stomachs, whereas Purdue's construction does not.

Depomed contends that a construction including fluid from non-human animal stomachs is supported by the intrinsic evidence. Depomed points to the claims themselves, arguing that they do not limit the type of gastric fluid that is covered. Depomed also argues that the written description similarly does not make any distinction

[18] Dkt. 121-1, Joint Claim Construction and Prehearing Statement; dkt. 132, Depomed's Opening Br.; dkt. 132-1 to dkt. 132-16, Andre I Decl.; dkt. 132-17 to dkt. 132-20, Appel I Decl.; dkt. 133, Purdue's Opening Br.; dkt. 133-1 to dkt. 133-3, Atwood Decl.; dkt. 133-4 to dkt. 133-5, Walsh I Decl.; dkt. 159, Purdue's Responsive Br.; dkt. 159-1 to dkt. 159-3, Walsh II Decl.; dkt. 161, Depomed's Responsive Br.; dkt. 161-1 to 161-6, Lee Decl.; dkt. 161-7, Appel II Decl.

between animal gastric fluid and human gastric fluid for the purpose of the claimed invention. In fact, Example 9 describes the testing of dosage forms in Beagle dogs in both the fed mode and not in the fed mode. See '475 Pat., col. 16, l. 43 – col. 17, l. 24. Depomed characterizes Purdue's construction as an attempt to add a limitation that would erroneously exclude the preferred canine gastric fluid embodiment of Example 9, which is a suitable model for the fluid in the human stomach.

Depomed acknowledges that Purdue's construction is the same as that in the Ivax case. However, Depomed argues that the Ivax construction did not limit the term gastric fluid to any specific type of gastric fluid. See Ivax, 2006 WL 3782829, at *7 ("The Court concludes that, although the patent is directed toward a drug dosage form that is ultimately for use in a patient, and therefore in the human stomach, the claims to the composition are not necessarily limited to that milieu. . . .").

Depomed's expert, Dr. Leah Appel, Ph.D., declares that "gastric fluid" would have been understood by a POSA to mean the fluid found in the gastrointestinal tract of both humans and animals. (Dkt. 132-17 at 10.)[19] Dr. Appel explains that animal tests are

[19] Purdue contends that Depomed should not be allowed to rely on Dr. Appel's conclusions because she did not stand by the definition she proposed in her report at her deposition. We do not rely on the extrinsic evidence to reach our construction of this claim term. See Phillips, 415 F.3d at 1318 (indicating that use of extrinsic evidence in claim construction is permissive, not mandatory (citing Markman, 52 F.3d at 980)). However, we note that we do not agree with Purdue's assertions that Dr. Appel abandoned the definition she proposed in her report. She stated that she did not disagree with the construction of the Lupin and Sun cases, and thought it was narrower than what she understood the term to encompass as a practicing formulator. (See dkt. 159-2 at 9-10.) Importantly, when asked what the term "the stomach" meant, Dr. Appel stated that it could be fluid in the stomach of a human and fluid in the stomach of an animal. (Id. at 11.)

routinely performed by POSAs to understand how oral dosage forms will release drugs in humans, and to determine their safety and efficacy. (Id.) In addition, POSAs may also use a simulated gastric fluid to perform dissolution tests *in vitro*. (Id. at 11.)

Purdue contends that "gastric fluid" can only mean "human gastric fluid" or "simulated human gastric fluid." Purdue, relying on the testimony of its expert, Dr. Atwood, argues that the description of simulated gastric fluid in the patent[20] is for simulated human gastric fluid. See dkt. 133-1 at 27. Purdue argues that since human stomachs are the stomachs for the models, they are the only relevant stomachs to the patents, and that it would not make sense for gastric fluid to encompass the gastric fluid of non-human animals. Id. Purdue further contends that the patents-in-suit do not describe drug dosage forms for any animals other than humans. Purdue argues that Example 9 does not describe a preferred embodiment of the invention because there is no drug in the dosage forms of Example 9, because that study was to demonstrate that the tablets are retained in the stomach longer in the fed mode compared to the fasted mode.

The Court has considered the parties' respective arguments and the relevant evidence. The Court adopts Depomed's proposed construction and construes the claim term "gastric fluid" to mean "both the fluid in the stomach and simulated or artificial fluids recognized by those skilled in the art as a suitable model for the fluid of the human stomach."

[20] The fluid used in the *in vitro* test of Example 1 was a "modified simulated gastric fluid" described as "7 mL of hydrochloric acid and 2 g of sodium chloride in 100 mL of deionized water; the enzyme pepsin was omitted." '475 Pat., col. 12, ll. 60-62.

There is no reason to limit the term "gastric fluid" to only "human gastric fluid." The term "gastric fluid" appears unmodified in the claims; and therefore, the claim language itself does not restrict the scope of this term's meaning. The term "stomach" is also unmodified in the claims. The limitations referencing the stomach discuss the properties that the dosage form must possess, e.g., the ability to attain a size large enough to promote retention in the stomach during the fed mode. The claims do not restrict the stomach to the human stomach, and therefore there is no inference that the term "gastric fluid" must be limited to that of the human stomach.

The written description similarly does not restrict this claim term directly or by inference. When describing a test subject, the written description repeatedly uses the terms "patient" and "subject" without any further qualification. The term "human" only appears twice in the entire written description. Both of those occurrences are found in the discussion of Example 9, which, as discussed above, illustrates the differences between human subjects and non-human animal subjects in various states. See '475 Pat., col. 16, l. 43 – col. 17, 24. By including an example that discusses non-human animal test subjects, the Court finds that the patentees did not intend to limit the term "gastric fluid" to only human gastric fluid. For this term, the intrinsic evidence alone wholly supports our construction. See Phillips, 415 F.3d at 1318 (Fed. Cir. 2005) (indicating that the use of extrinsic evidence in claim construction is permissive, not mandatory (citing Markman, 52 F.3d at 980)).

The Court is not persuaded by Purdue's argument that Example 9 should not be considered. Example 9 is concerned with one of the claimed aspects of the invention, the

retention of the dosage form in the stomach, and is therefore relevant regardless of whether it has an incorporated drug or not.

Accordingly, the Court adopts Depomed's proposed construction and construes the claim term "gastric fluid" to mean "both the fluid in the stomach and simulated or artificial fluids recognized by those skilled in the art as a suitable model for the fluid of the human stomach."

2. "Remains substantially intact"

Depomed's proposed construction for this claim term is taken verbatim from the definition provided in the written description. See '475 Pat., col. 9, ll. 34-41 ("The term 'substantially intact' is used herein to denote a polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles."). Depomed argues that this definition is dispositive and that Purdue's proposed construction improperly restricts the substantial intactness of the polymeric matrix to a specific portion of the matrix, i.e., the "swollen" portion. Depomed also argues that the written description discusses the polymeric matrix swelling in the context of the size that it achieves, not as the portion of the matrix that remains intact.

Depomed's expert, Dr. Appel, declares that the patentees' definition for this term is consistent with the meaning to a POSA, and that the intactness of the dosage form is not restricted to any specific portion of the matrix. (See dkt. 132-17 at 22-23.) She explained that:

> A [POSA] understands that for a "polymeric matrix" to "remain substantially intact" in the context of the patents, means the polymeric matrix as a whole. This includes both the swollen portion and the non-swollen portion of the "polymeric matrix" that "remains substantially intact," without necessarily restricting the intactness to the swollen or to the non-swollen portions in isolation.

(Id. at 23.)

Purdue contends that the swollen portion of the polymeric matrix must retain its swollen size. Purdue, citing the written description, argues that the purpose of the invention, i.e., controlling the location of the dosage form in the stomach, can only be achieved if the polymer retains the size and shape of the swollen form and does not disintegrate or break into small particles. (See dkt. 133 at 33-34.) Purdue's expert, Dr. Atwood, explains that "[t]he only way for the formulation to remain in the stomach and not pass through the pylorus, in this scheme, is if the *swollen* polymer portion substantially retains its size and shape. If the swollen portion deteriorates, then the formulation will shrink back to the oral dosage form's original size, which could pass through the pylorus." (Dkt. 133-1 at 28.) Because the swollen form is the essence of the invention, according to Purdue, Purdue asks this Court to clarify that the *swollen* polymer portion is what must substantially retain its size and shape.

The Court has considered the parties' respective arguments and the relevant evidence. The Court adopts Depomed's proposed construction and construes the claim term "remains substantially intact" to mean "a polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles."

The patentees provided a definition for this term in the specification. See '475 Pat., col. 9, ll. 34-41. That definition does not restrict the substantial intactness of the polymeric matrix to a specific portion of the matrix. Generally, "[t]he patent's specification is the 'single best guide to the meaning of a disputed term.'" Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). When an inventor defines a term in the specification, "the inventor's lexicography governs." Id. at 1316. Because the applicants chose to be their own lexicographer, that definition shall govern. The Court is unpersuaded by Purdue's arguments, and declines to further limit the definition explicitly provided by the patentees.

Accordingly, the Court construes the claim term "remains substantially intact" to mean "a polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles."

3. "Until all of said drug is released"

For this term, the disagreement between the parties is over the amount of drug that must be released to constitute "all" of the drug being released. As discussed above, the two district courts that have construed this term have sided with Depomed. In Sun, Judge Pisano acknowledged that "[t]he '475 Patent discloses that the dosage form will not always, and often does not, release 100% of the incorporated drug," but noted that there was "nothing else in the intrinsic evidence to assist the Court in determining what meaning the patentees intended to give 'all of said drug.'" Sun, 2012 WL 3201962, at *12. Judge Pisano ultimately adopted Depomed's construction, relying on Judge

Hamilton's construction in Lupin, the extrinsic evidence cited by Depomed, and Depomed's arguments pertaining to the exclusion of preferred embodiments. See id.

In Lupin, Judge Hamilton determined that she needed to construe the term in a way that distinguishes it from the term "until substantially all of said drug is released," which was construed in that case to mean "at least 80% of the drug is released." Lupin, 2011 WL 1877984, at *12. Based on the specification, the extrinsic evidence, and expert testimony, Judge Hamilton adopted Depomed's construction, noting that the evidence supported a construction of "100% or something less than 100%." Id. at *13. Judge Hamilton, however, did not elaborate with respect to what "something less than 100%" meant. See id.

The PTAB declined to adopt Depomed's construction for this term, and instead construed the term according to its plain, ordinary meaning:

> The plain meaning of "until *all* of said drug is released" is evident. If we were to adopt Patent Owner's argument that "all" can mean "less than all," we would be ignoring the plain meaning of the term. Moreover, although Patent Owner is correct that certain other embodiments in the Specification plateau at less than 100% of drug release, we note that certain embodiments do plateau at 100%. See ['475 Pat.], Fig. 1 (curve marked by filled diamonds); see also August Tech. Corp. v. Camtek, Ltd., 655 F.3d 1278, 1285 (Fed. Cir. 2011) ("The mere fact that there is an alternative embodiment disclosed in the [asserted patent] that is not encompassed by [our] claim construction does not outweigh the language of the claim, especially when [our] construction is supported by the intrinsic evidence." (citation omitted)).
>
> Furthermore, as noted above, we have determined that, as properly construed, the phrase "releases substantially all" in claim 43 means "at least 80% of the drug has been released." If we were to interpret "all" to mean the point at which the drug

> release profile plateaus—even if less than 80%—then it would be possible for a dosage form to release "all" of a drug, but not "substantially all" of the drug. Such an inconsistency within the claim would not be a reasonable construction of the term "all." Accordingly, we decline to construe "until all of said drug is released" as broadly as Patent Owner requests and, instead, construe it according to its plain, ordinary meaning.

(Dkt. 132-14 at 9-10.)

Here, Depomed raises the same or similar arguments it made in these prior proceedings. Depomed acknowledges that its proposed construction diverts from the plain and ordinary meaning of the term "all," and argues that the term has a "special meaning" in the context of the patents-in-suit. According to Depomed, the release of "all" of said drug means the time when the plateau of the dissolution profile has been reached, which may be at a point when less than 100% of the drug is released. Depomed's expert, Dr. Appel, explains that:

> In sustained release dosage forms there is often some drug that doesn't exit the dosage form within a relevant time frame (duration of dissolution test or time it takes to transit the entire GI tract). Formulation scientists therefore look at the plateau of the dissolution profile as representing all the drug that will be released in a relevant time frame. There was not an expectation that all sustained release formulations release 100% of the drug contained in them now or at the time of the filing of the patents in 1997.

(Dkt. 132-17 at 20-21.) Stated differently, the dissolution profile is the point when all of the drug that is going to be released, is released, which may be at an amount less than 100%.

To support its position, Depomed points to Example 1 of the patents-in-suit. Example 1, supported by Figure 1 (reproduced below), shows three dosage forms, only one of which releases 100% of the incorporated drug after nine hours.

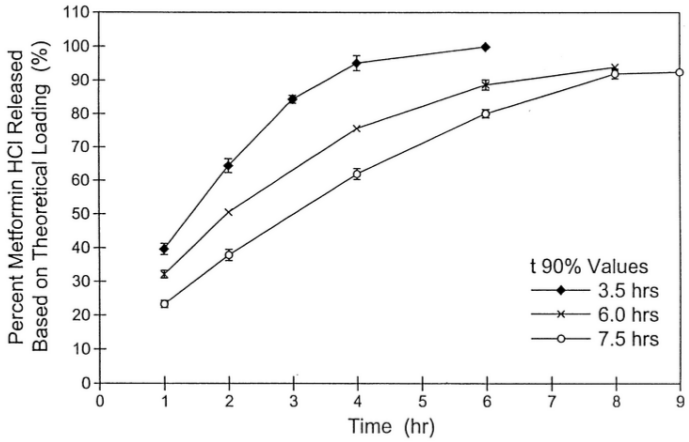

Fig. 1

'475 Pat., Fig. 1. The other two dosage forms plateau in the same timeframe at a release point of 90% of the incorporated drug. According to Depomed, all of these examples would be viewed by the POSA as constituting "all of the drug" being released.

Depomed also relies on two FDA guidance documents.[21] Dr. Appel summarizes those documents as follows:

> [T]he FDA Dissolution Guidance explains that there should be a minimum of three time points for a dissolution study: "early, middle and late," the last of which "should be the time point where at least 80% of drug has dissolved," and "[if] the maximum amount dissolved is less than 80%, the last point should be the time when the plateau of the dissolution profile has been reached."

[21] The FDA documents are: (1) Food and Drug Administration, Guidance for Industry: SUPAC-MR: Modified Release Solid Dosage Forms (1997) (dkt 132-15); and (2) Food and Drug Administration, Guidance for Industry: Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (1997) (dkt. 132-16).

> Similarly, the FDA SUPAC Guidance explains that the endpoint of dissolution testing should occur "until either 80% of the drug from the drug product is released or an asymptote is reached."
>
> Both of the FDA guidances illustrate that it is not expected that all of the drug is released in sustained release dosage forms and therefore the plateau or asymptote of the dissolution profile is taken as showing the release of all the drug that is going to be released within a relevant time frame.

(Dkt. 132-17 at 21 (citations omitted).) It is therefore Depomed's position that these guidances support its construction and the understanding of the POSA that the term "all" would cover something less than 100% in this context. Finally, as it did in the previous cases, Depomed argues that a construction requiring 100% release would read out the preferred embodiments where less than 100% of the drug is released. The Court notes that while Depomed argues that all means less than 100%, it does not provide a floor or a range for the meaning of the term.

Purdue contends that "all of said drug" should be given its plain and ordinary meaning of 100%. Purdue argues that the POSA's understanding of the term would not have differed from how the term is generally understood. On this point, Purdue offers three dictionary definitions, each defining the word "all" as an "entire" or "total" amount, and the testimony of Dr. Atwood. (See dkt. 133-1 at 7.)[22] Depomed, however,

[22] American Heritage Dictionary (2d. ed. 1985) (defining "all" as "[t]he entire or total number, amount, or quantity of") (dkt. 133-5 at 83-86); Webster's II: New College Dictionary (1995) (defining "all" as "[t]he whole number, amount, or quantity of") (dkt. 133-5 at 88-90); Webster's Ninth New Collegiate Dictionary (1989) (defining "all" as "the whole amount or quantity of") (dkt. 133-5 at 92-95).

characterizes Purdue's reliance on these dictionaries as improper because they are general-purpose dictionaries that predate the priority dates of the patents.

Purdue also makes multiple arguments based on intrinsic evidence. Focusing on the language of claim 1 of the '475 Patent, Purdue states that the "drug" is first defined in that claim as the "drug dispersed [in the solid polymeric matrix] at a weight ratio of drug to polymer of from about 15:85 to about 80:20." See n. 8, supra. Purdue contends that this language refers to the amount of drug present in the claimed controlled release dosage form, and that therefore "all of said drug" is all of the drug present in that formulation. (See dkt. 133 at 11-12.) Purdue also notes that the term "all" is consistently used throughout the patents-in-suit to mean 100%. See '475 Pat., cover page ("all of" the inventors reside in California); col. 3, l. 37 ("all of these variations"); col. 4, l. 32 ("all of these drugs").

With respect to the examples provided in the written description, Purdue acknowledges that some examples show less than 100% release of the drug, but argues that the patents-in-suit also provide multiple examples showing 100% release of the drug. See id., Figs. 1, 3, and 4. Purdue argues that in these examples the amount of drug released is reported based on either actual or theoretical loading of drug in the formulation, not when the drug hits a plateau, which suggests that the important metric is the percentage of drug released relative to 100% drug loading.

With the testimony of Dr. Atwood, Purdue argues that the "goals" of the invention (i.e., extending the time of delivery into the stomach and confining delivery and absorption of the drug to the upper GI tract) support a construction requiring "all" or

100% of said drug. Dr. Atwood declares that "[i]f less than 100% of the drug was released [] before the dosage form deteriorated so that it was no longer substantially intact, the dosage form would leave the stomach. Thus the remaining drug release would not be confined to the stomach and upper intestine." (Dkt. 133-1 at 10.) In addition, Dr. Atwood explains that "[r]eleasing all of the drug while the dosage form remains substantially intact allows the claimed dosage form to avoid [transient overdose]; retaining some of the drug in the dosage form until the time when the dosage form disintegrates might lead to transient overdose." (Id.)

Purdue further contends that Depomed's proposed construction creates ambiguities and inconsistencies. Purdue contends that Depomed fails to adequately articulate what is meant by the "plateau of the dissolution profile." Dr. Atwood declares that the POSA would not understand a plateau in drug release to necessarily mean that "all" of the drug has been released from the formulation, or even that release of drug from the formulation is complete. He explains that "formulations may exhibit pulsatile release, characterized by a plateau followed by a period of rapid drug release." (Id. at 11.)[23] He also explains that artificial plateaus may be exhibited under certain conditions:

> [I]f sink conditions do not exist in the dissolution test, the drug release might artificially plateau due to the lack of concentration gradient to drive drug release. Sink conditions exist when the volume of dissolution media is at least three times greater than the volume at the saturation point of the drug contained in the drug delivery system being tested. If the drug concentration in the surrounding dissolution media is

[23] On this point, Dr. Atwood cited Singh, D.K., International Journal of Current Pharmaceutical Review and Research, V. 2:2, May-July 2011. (Dkt. 133-2 at 80-106.)

> saturated, the dissolution profile will plateau, even if there is a significant amount of drug left in the dosage form.

(Dkt. 133-1 at 11 (citation omitted).)[24] Depomed attacks these positions as irrelevant, arguing that the patents-in-suit do not concern pulsatile release. (See dkt. 161 at 39-40.)

Finally, Purdue argues that Depomed's construction for this term and its construction for "substantially all of said drug" would lead to the inconsistent situation identified by the PTAB where a dosage form could release "all" of a drug, but not "substantially all" of the drug, if a plateau occurs at less than 80%.

The Court has considered the parties' respective arguments and the relevant evidence. The Court adopts Purdue's proposed construction and construes the claim term "until all of said drug is released" to mean "[until] 100% of the drug has been released."

"[T]he words of a claim 'are generally given their ordinary and customary meaning.'" Phillips, 415 F.3d at 1312 (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The "ordinary and customary meaning" is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Id. at 1313. "Properly viewed, the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent." Id. at 1321.

The Court finds that "all" in the context of the claims means "all" or "100%." The Court agrees with Judge Pisano that there is little intrinsic evidence to assist the Court in determining what meaning the patentees intended for "all of said drug." The patentees

[24] On this point, Dr. Atwood cited Vaghela, B., et al., Journal of Applied Pharmaceutical Science 01 (03); 2011: 50-56. (Dkt. 133-2 at 108-114.)

did not act as their own lexicographer with respect to this term, as they chose to with other terms. See Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) ("To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning." (quotations omitted)). The examples in the written description relied on by Depomed do show the release of a drug at less than 100% for some dosage forms. However, a claim need not cover every disclosed embodiment in the specification. See August Tech. Corp. v. Camtek, Ltd., 655 F.3d 1278, 1285 (Fed. Cir. 2011) ("The mere fact that there is an alternative embodiment disclosed in the [asserted patent] that is not encompassed by [our] claim construction does not outweigh the language of the claim, especially when the court's construction is supported by the intrinsic evidence." (citation and internal quotation marks omitted)); see also Baran v. Medical Device Techs., Inc., 616 F.3d 1309, 1316 (Fed. Cir. 2010) ("It is not necessary that each claim read on every embodiment."). The examples clearly include dosage forms that do indeed release 100% of the drug. See, e.g., '475 Pat., Fig. 1.

As the PTAB correctly noted, Depomed's proposed construction creates an irreconcilable inconsistency between this term and the term "substantially all of said drug," as we construe it below. If this Court were to interpret "all" to mean the point at which the drug release profile plateaus, a dosage form that plateaus at 50% release would fall within the bounds of "all", but not within the bounds of "substantially all." Similarly, a dosage form that plateaus at 80% release would fall within the bounds of both "all" and "substantially all." The claim term "substantially all" most certainly must be less than

"all." Such an inconsistent situation persuades this Court that the plain, ordinary meaning should control.

Accordingly, the Court construes the claim term "until all of said drug is released" to mean "[until] 100% of the drug has been released."

4. Claim terms concerning swelling upon imbibition of water or gastric fluid

For the claim terms concerning swelling upon imbibition of water or gastric fluid, the dispute between the parties concerns two issues: (1) whether the construction should include a specific size that the polymeric matrix must swell to in order to promote retention in the stomach; and (2) whether the construction should include a specific amount of time that matrix must remain in the stomach. Depomed's proposed constructions do not include specific dimensions or time amounts. Purdue's proposed constructions, on the other hand, do.

With respect to the "size" issue, Depomed argues that the intrinsic and extrinsic evidence supports its constructions. First, Depomed argues that the written description never limits the swollen polymeric matrix to a minimum size. Depomed contends that the swollen size is discussed in only functional terms, which counsels against construing the terms to include specific dimensions of the swollen tablet. See id., col. 5, l. 66 – col. 6, l. 3 (the matrix "swells upon ingestion, preferably to a size that is at least about twice its unswelled volume, and that promotes gastric retention during the fed mode"); col. 6, ll. 19-21 ("the tablet swells to a size large enough to cause it to be retained in the stomach during the fed mode"); col. 9, ll. 1-5 (the matrices "swell in size . . . to achieve a size that

will be retained in the stomach when introduced during the fed mode"). The only specific dimensions that are provided in the written description are of tablets in unswollen states, which range in size from 3mm to 22mm. See id., col 10, ll. 20-39; col. 13, ll. 27-33; col. 14, ll. 6-36, 48-50; col. 14, l. 61 – col. 15, l. 40; col. 15, ll. 51-59; col. 16, ll. 3-31, 54-57; col. 17, ll. 14, 35-36.[25] Depomed argues that if the smaller of these tablets (i.e., the 3 mm and 4 mm tablets) were to swell to the preferred at least about twice unswelled volume, these swollen tablets would still fall short of the 9.5 mm dimensions sought by Purdue. Depomed also argues that the phrase "when swollen in a dimensionally unrestricted manner," found in the claims of the '280 Patent, should be given its plain, ordinary meaning,[26] and should not be limited to at least two directions.

Depomed's expert, Dr. Appel, opines that a pharmaceutical formulation may not need to swell to the size suggested by Purdue to promote retention in the stomach during the fed mode. (See dkt. 132-17 at 14.) Dr. Appel declares that in 1997, the POSA understood that there was no *per se* cutoff for gastric retention. (Id.)[27] Dr. Appel also

[25] The written description notes that these "shapes and sizes can be varied considerably." Id., col. 10, ll. 38-39.

[26] Depomed's expert, Dr. Appel, declares that the POSA would understand the plain, ordinary meaning of "when swollen in a dimensionally unrestricted manner" to be "that swelling of the dimensions of the dosage form [do] not have any restriction." (Dkt. 132-17 at 13.)

[27] Dr. Appel cites C, Timmermans J. Moes A.J., The cutoff size for gastric emptying of dosage forms, J. Pharm. Sci. 82, 8:854 (1993), which states that "there is no exact cutoff size per se but a gradation of sizes over which predictable emptying from a fed stomach becomes uncertain and highly variable."

references excerpts of a 1989 book chapter,[28] cited by Purdue, stating that particles above 4 mm may be passed not at all or only slowly from the food filled stomach." (Id.)[29]

Purdue argues that the size of the particles must logically be tied to the size of the pylorus. The written description explains that in order to retain particles in the stomach, the particles must swell to a size greater than that of the pylorus. '475 Pat., col. 11, l. 65 – col. 12, l. 4. ("Indigestible particles greater than the size of the pylorus are retropelled and retained in the stomach. Particles exceeding about 1 cm in size are thus retained in the stomach for approximately 4 to 6 hours. The dosage form of the present invention is designed to achieve the minimal size through swelling . . . .").

Purdue's expert, Dr. Atwood, declares that to be greater than the size of the pylorus, a formulation must swell in at least two directions. (See dkt. 133-1 at 24-25.) To support his position, Dr. Atwood cites the use of the term "dimensionally unrestricted manner" in the patents-in-suit and the size descriptions of the unswollen tablets given in multiple dimensions. Dr. Atwood also states that swelling in at least two dimensions is important to achieving gastric retention, and that a POSA "would understand that a dosage form that is longer than the pyloric sphincter but whose diameter is less than the pylorus may not be retained; it could exit through the pylorus when its long axis pointed

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[28] Hardy, et al., Drug delivery to the gastrointestinal tract, Wilson. Ellis Horwood Limited, 1989.

[29] The excerpt from Hardy states: "[P]ostcibal gastric transit of particles is characterized by high discrimination so that particles of food mostly 1 mm or less are emptied; a size which is readily digestible. Similarly particles of drug or plastic at or below this size are rapidly passed. Particles 1-3mm in diameter are passed more and more slowly as the size increases over this range, and particles above 4 mm may be passed not at all or only slowly from the food filled stomach." (Dkt. 132-19 at 6.)

directly at the pylorus." (Dkt. 133-1 at 24.) Dr. Atwood opines that a POSA would understand 1 cm to mean not less than 9.5 x 9.5 mm. (Id.) He states that despite conflicting reports in the literature at the time of the invention concerning the size of dosage forms that are retained in the stomach, it was recognized that objects less than 8 mm are not reliably retained in the stomach during the fed mode, and that between 7-10 mm there is a gradation of size over which predictable emptying from the fed stomach becomes uncertain and highly variable. (Id.)[30] Dr. Atwood concludes that given this information, a POSA would have been taught away from using formulations less than 10mm. (Id. at 25.)

Purdue also argues that Depomed disclaimed embodiments that only swell in one dimension during the IPR proceedings.[31] Depomed refutes this point, and argues that its

[30] On this point, Dr. Atwood relies on the Declaration of Dr. Hopfenberg submitted on behalf of Depomed in the Ivax case, which cited Khosla et al., Gastrointestinal Transit of Non-Disintegrating Tablets in Fed Subjects, Int'l J. for Pharmaceutics 53, 107-117 (1989) and Jacques Timmermans & Andre J. Moes, The Cutoff Size for Gastric Emptying of Dosage Forms, J. Pharm. Sci., 82, 854 (1993). (See dkt. 133-3 at 54-98.)

[31] In its Preliminary Response to the Petition for Inter Partes Review of U.S. Patent No. 6,340,475, Depomed attacked a prior art reference asserted by Purdue as follows:

> Even if the data on dosage forms containing alprenolol HCL (lacking the requisite solubility) set forth in the Park report is analyzed, it is clear that the data do not satisfy swelling to a size sufficient to promote retention in the stomach in the fed mode. Claim 1 recites that the polymeric matrix is one that swells to attain a size large enough to promote retention in the stomach during said fed mode. The data in the Park report tabulate the swelling parameters of the dosage form only in terms of a single dimension – the diameter – and states that Park's tests confirm Baveja's formulations swell to about 13.5 – 14.5 mm. Purdue provides no information regarding the thickness of the dosage form. It is conceivable that the tablets disclosed by Baveja and reproduced for the data in the Park report would not provide the necessary swelling

statements during the IPR proceedings do not operate as a clear disavowal of claim scope. Depomed asserts that it was attacking Purdue's expert's (Park) unreliable methodologies and failure to disclose the thickness dimension of the reproduced tablets.

With respect to the "time" issue, Depomed argues that the intrinsic evidence supports its construction. Depomed points to the abstract, which does not give a specific time amount that the swollen matrix must remain in the gastric cavity. Instead, the abstract states that the dosage form is retained for "several hours." See '475 Pat., abstract. Depomed also points to a portion of the Summary section that discusses the objectives of the polymeric matrix; one being to retard the rate of diffusion of a drug to provide multi-hour, controlled delivery in the stomach. See id., col. 6, ll. 18-24. Depomed acknowledges that the written description states that "particles exceeding about 1 cm in size are thus retained in the stomach for approximately 4 to 6 hours," id, col. 11, l. 67 – col. 12, l. 2, but argues this is a single embodiment that should not be read into the claims. Depomed argues that Purdue's construction would exclude the embodiments illustrated in Examples 1, 4, and 6, that each show a formulation that releases 90% or more of a drug in less than 4 hours.

Purdue argues that the term "remains in the stomach for several hours" must be confined to a specific time period. Purdue argues that the written description explains that the fed mode typically lasts only 4 to 6 hours, and thus the "several hours" refers to

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> in their thickness dimension to be of a size large enough to promote retention in the stomach in the fed mode.

(Dkt. 133-5 at 184.)

the length of time of the fed mode. See '475 Pat., col. 2, ll. 19-20 ("the duration of the fed mode . . . typically lasts for only 4 to 6 hours"). Purdue also argues that the written description consistently describes the length of time that the formulation remains in the stomach as at least four hours. See id., col. 3, ll. 3-7 ("The swellable hydrophilic matrix of the present invention protects the yet undelivered drug during the 4 to 6 hour delivery period during which the drug is continuously released while the dosage form is retained in the stomach."); col. 11, l. 67 – col. 12, l. 2 ("Particles exceeding about 1 cm in size are thus retained in the stomach for approximately 4 to 6 hours."); col. 17, ll. 19-21 ("In the fed trials, the tablets demonstrated multiple-hour retention in the stomach in all subjects, 80% of the contents of all tablets being retained at 4 hours."). Purdue contends that these discussions are more relevant than the general disclosures that Depomed relies on. With respect to example 1 (showing release of 90% or more of a drug in less than 4 hours), Purdue contends that this example should not be considered because it does not discuss retention in the stomach.

The Court has considered the parties' respective arguments and the relevant extrinsic evidence. For the following reasons, the Court adopts Depomed's proposed constructions.

The claims themselves do not provide specific swollen dimensions for a dosage form. Instead, as Depomed correctly points out, the patentees chose to claim the size functionally. See, e.g., '475 Pat., col. 17, ll. 52-53 ("attaining a size large enough to promote retention in the stomach during said fed mode."). Similarly, the written

description does not provide specific swollen dimensions for the dosage forms. The discussion regarding the pylorus and particle size is also far from conclusive:

> Indigestible particles greater than the size of the pylorus are retropelled and retained in the stomach. Particles exceeding about 1 cm in size are thus retained in the stomach for approximately 4 to 6 hours. The dosage form of the present invention is designed to achieve the minimal size through swelling following ingestion during the fed mode.

Id., col. 11, l. 65 – col. 12, l. 4. The Court does not view this passage as setting a limit to the particle size sufficient to be retained in the stomach. The patents-in-suit do not articulate a size, or range of sizes, for the pylorus. They merely state that particles larger than that part of the stomach will be retained. It is clear that particles exceeding about 1 cm in size will be retained, however the use of the word "about" suggests that something less may also be retained. The final sentence referring to "the minimal size" is partly unclear. The term "minimal size" is not defined in the patents-in-suit. This sentence could refer to "about 1 cm" or it could generally refer to the minimal size needed for retention in the stomach.

Purdue's construction cannot be correct. As discussed above, the written description does provide dimensions for unswollen tablets. If certain of these tablets were to swell to their preferable size that is at least about twice its unswelled volume, their dimensions would fall short of the 9.5 mm x 9.5 mm limitation proposed by Purdue. Adopting Purdue's construction would therefore exclude preferred embodiments. Adams Respiratory Therapeutics, Inc. v. Perrigo Co., 616 F.3d 1283, 1290 (Fed. Cir. 2010) ("A claim construction that excludes [a] preferred embodiment 'is rarely, if ever, correct and

would require highly persuasive evidentiary support.'" (quoting Vitronics Corp. v. Conceptronic Inc., 90 F.3d 1576, 1583-84 (Fed. Cir. 1996)).

The Court appreciates Purdue's argument that swelling in more than one dimension can be important to achieving gastric retention. However, we do not read Depomed's statements to the PTAB as amounting to a clear and unmistakable disclaimer of swelling in only one direction. See 3M Innovative Props. Co. v. Tredegar Corp., 725 F.3d 1315, 1325 (Fed. Cir. 2013) ("[I]n order for prosecution disclaimer to attach, the disavowal must be both clear and unmistakable."). Where the alleged disavowal is ambiguous, or even amenable to multiple reasonable interpretations, the Federal Circuit has counseled against finding disclaimer. See Avid Tech., Inc. v. Harmonic, Inc., 812 F.3d 1040, 1045 (Fed. Cir. 2016). Depomed's statements to the PTAB can reasonably be interpreted as arguing that Purdue had not met its burden because the reference was unclear as to whether the tablet would be retained in the stomach. Accordingly, we do not find disclaimer that would require us to construe the claim term to include two dimensions. We note that even if we did find disclaimer, we would not adopt the dimensions set forth by Purdue for the reasons stated above. We also decline to replace the dimensions proposed by Purdue with dimensions of our own choosing. We believe such an act would be improper. As Judge Breyer noted in the Ivax case, "[a] patentee has the right to claim the invention in terms that would be understood by persons of skill in the art, and "mathematical precision should not be imposed for its own sake." Ivax, 2006 WL 3782829, at *13 (citation omitted).

In addition, for the reasons stated above, we also find that the phrase "when swollen in a dimensionally unrestricted manner," found in the claims of the '280 Patent, should be given its plain, ordinary meaning and should not be limited to at least two directions. Nothing in the intrinsic or extrinsic evidence requires us to import such a limitation.

With respect to the "time" issue, we decline to adopt the limitations proposed by Purdue. The intrinsic evidence supports our construction. The claim terms at issue do not include a specific time limitation. They each state that swelling promotes "retention in the stomach **during said fed mode**." See, e.g., '475 Pat., col. 17, ll. 52-53 (emphasis added). We agree with Purdue that the written description states that the fed mode "typically lasts for only 4 to 6 hours," however, nothing in the claims requires the dosage form to remain in the stomach for the entirety of the fed mode. Other language found in the written description also counsels against drawing an artificial line at 4 hours. See, e.g., id., col. 11, l. 67 – col. 12, l. 2 ("Particles exceeding about 1 cm in size are thus retained in the stomach for **approximately** 4 to 6 hours." (emphasis added)). The use of the term "approximately" in this context is evidence that the patentees did not intend to put forth a limitation requiring the dosage form to remain in the stomach for at least 4 hours.

Accordingly, we construe the term "said polymeric matrix being one the swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode" and "said polymeric matrix being one that swells upon imbibition of gastric fluid to a size large enough to promote retention in the stomach

during said fed mode" to mean "the dosage form, which comprises a polymeric matrix, increases in size due to the ingress of [water/gastric fluid], such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours." With respect to the claim term "when swollen in a dimensionally unrestricted manner as a result of imbibition of [water/gastric fluid] is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode" found in claims 1 and 43 of the '280 Patent, we construe the former part of that term, "when swollen in a dimensionally unrestricted manner as a result of imbibition of [water/gastric fluid]," to have its plain, ordinary meaning. We construe the latter part, "is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode," to mean "such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours."

5. Claim terms concerning "substantially all of said drug"

Purdue has not proposed a construction for the terms including the phrase "substantially all of said drug." Instead, Purdue maintains that these claim terms are indefinite.

As discussed above, some of these claim terms have been construed by three other district courts.[32] However, those courts were not asked to consider the question of

[32] One of the three district courts simply accepted the construction agreed to by the parties. See Section I.B.5, supra.

indefiniteness. In Ivax, the parties' dispute over the term "substantially all" was purely quantitative. Depomed sought a construction of "about 80%" and Ivax sought a construction of "at least 90%." See Ivax, 2006 WL 3782829, at *4. Both parties argued that the intrinsic evidence, specifically the examples illustrating drug release, supported their respective positions. See id. Judge Breyer found the parties' competing contentions to be reasonable, but found the intrinsic evidence to be an "inadequate basis for a definitive construction of the disputed term." Id. As a result, Judge Breyer turned to the extrinsic evidence, specifically the FDA Guidance documents, and adopted Depomed's proposed construction. Id. at *5 ("In the absence of any strong indication in the intrinsic record as to the boundary of the vague and approximate term 'substantially all,' the extrinsic FDA source offers the clearest insight into the understanding that one of skill in the art would have of the term.").

In Sun, the parties' dispute was again quantitative in a sense. Sun argued that the plain, ordinary meaning of "about 100%" should apply, and Depomed maintained its position that the proper construction was "at least 80%." See Sun, 2012 WL 3201962, at *10. Judge Pisano expressed the same apprehension toward the intrinsic evidence as Judge Breyer, see id., at *11 (noting that the examples "reveal wide, varying release rates at the eight hour mark, thereby making the meaning of 'substantially all' unclear" and "[a]t the very least, the specification demonstrates that the patent applicants meant something other than 'about 100%'"), and agreed with and deferred to Judge Breyer's reliance on the FDA Guidance documents in adopting Depomed's construction.

Purdue acknowledges the previous construction history of these terms, but argues that the standard for proving indefiniteness is now less demanding after the Supreme Court's decision in Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120 (2014). In Nautilus, the Supreme Court rejected the Federal Circuit's "unsolubly ambiguous" standard for indefiniteness. See id. at 2124. The Court held that "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent and prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Id. Following Nautilus, the Federal Circuit reiterated that "general principles of claim construction apply" to the question of indefiniteness. Biosig Instruments, Inc. v. Nautilus, Inc., 783 F.3d 1374, 1377 (Fed. Cir. 2015) (internal quotation marks omitted). The Federal Circuit also explained that, in its view, Nautilus did not imply that terms of degree are inherently indefinite. Id. at 1378. Terms of degree are definite when they provide "enough certainty to one of skill in the art when read in the context of the invention." Id. (citation omitted).

Purdue argues that the intrinsic evidence fails to inform, with reasonable certainty, the meaning of the phrase "substantially all of said drug." Purdue contends that the claim language itself is vague, and that the specification does not provide an express definition for the term "substantially all." (See dkt. 133 at 17-20.) Purdue describes Depomed's "at least 80%" construction as a "completely arbitrary selection unsupported by the intrinsic record," and argues that because the examples and figures exhibit widely-varying release percentages, a POSA would not be reasonably certain when "substantially all" of the drug has been released. (See id. at 20.) Purdue further argues that the patentees were capable

of using more precise language than the ambiguous "substantially all" language, as evidenced by the patentees' choice to describe the amount of drug retained as "at least about" a certain percentage. (See id. at 21-22.)

Purdue contends that the extrinsic evidence, namely the FDA Guidances, does not save Depomed's claims from being indefinite. Purdue argues that nothing in the intrinsic record suggests that a POSA would focus on these specific FDA Guidances. (See id. at 23-24.) Purdue notes that the FDA Guidances never use the phrases "all of" or "substantially all of" to describe drug release and were not published until after the effective filing date of the patents-in-suit. (Id. at 24.)

Purdue also argues that the FDA Guidances deal with a different issue from the patents-in-suit. (See id.) Purdue's expert, Dr. Atwood, declares that the FDA Guidances "relate to dissolution testing for a very specific purpose: determining how similar the release profiles are between two formulations." (Dkt. 133-1 at 17.) He opines that the FDA Guidances "do not provide general guidance for dissolution testing or otherwise relate to a determination of whether substantially all of the drug has been released from a formulation." (Id.) He states that these documents provide "recommendation[s] for sampling times," in particular "a minimum of three time points covering the 'early, middle, and late stage of the dissolution profile.'" (Id. at 19 (citation omitted).) He explains that the last point "is recommended to be where at least 80% of the drug has dissolved, unless the maximum amount dissolved is less than 80%, where the last time point should be when the plateau of the dissolution profile is reached." (Id.) He further argues that the 80% mark has nothing to do with the meaning of the term "substantially

all of the drug" because the 80% point was chosen by the FDA "[i]n order to prevent results skewed toward a finding of similarity" because "formulations may have very similar release profiles after 80% of the drug is released." (Id. at 19-20.) Dr. Atwood argues that the literature explains that it is generally best to characterize the entire release profile. (Id. at 20.)[33] He argues that when the literature discusses "essentially complete" release, the literature does not use the 80% benchmark. (Id. at 20-21.)[34] He further argues that the 80% time point is a function of the way POSAs assess the lot-to-lot quality of a drug product. (See id. at 21.)

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[33] On this point, Dr. Atwood cites P.J. Skelly et al., Report of Workship on In Vitro and In Vivo Testing and Correlation for Oral Controlled/Modified-Release Dosage Forms, Journal of Pharm. Sciences, September 1990, Vol. 79, No. 9, at 853, which states:

> At a minimum, at least three time points are recommended, but more are strongly encouraged: a 1-h time point to assure that there is no dose dumping, a second time point around 50% dissolution, and a third time point around 80% dissolution. However, generally, it is best to characterize the entire in vitro release profile.

(Dkt. 133-3 at 42.)

[34] Dr. Atwood relies on USP 23 § 1088, In Vitro and In Vivo Evaluation of Dosage Forms (1995), which states:

> At least three test times are chosen to characterize the in vitro drug release profile for pharmacopeial purposes. Additional sampling times may be required for drug approval purposes. An early time point, usually 1 to 2 hours, is chosen to show that potential dose dumping is not probable. An intermediate time point is chosen to define the in vitro release profile of the dosage form, and a final time point is chosen to show essentially complete release of the drug. Test times and specifications are usually established on the basis of an evaluation of drug release profile data.

(Id. at 48.)

Purdue also argues that the POSAs did not consider only the 80% release rate in evaluating dissolution profiles. Purdue argues that a 90% release rate was both considered and employed prior to the publication of the FDA Guidances. (See id. at 23-24.)[35]

Depomed disagrees with Purdue's position that the "substantially all" claim terms are indefinite under the standard announced in Nautilus. Depomed argues that Purdue's evidence fails to demonstrate that the claim terms are not reasonably capable of being construed and understood by a POSA, and attacks Purdue's positions as devoid of proper context. (See dkt. 132 at 26-28.) Depomed stresses that the prior history regarding the construction of these terms, i.e., by multiple district courts, the PTAB, and many experts, demonstrates that these claim terms are capable of construction and are not indefinite. (See id. at 26-27.)

Depomed argues that its construction for this term is supported by the intrinsic evidence, pointing to a statement in the Summary section referring to a "majority of the drug" being released, and multiple examples that show at least 80% of the drug being released within ten hours. See '475 Pat., col. 6, ll. 10-15; col. 12, l. 10 – col. 13, l. 8; col. 13, l. 65 – col. 14, l. 50; col. 15, ll. 43-60; Figs. 1, 4, 5, and 7.

[35] Purdue cites FDA Approval Package for NDA 20-616/S-001 (July 29, 2007) (Dkt. 133-3 at 32) and International Patent Publication No. WO 92/04013 (Dkt. 133-5 at 140-158.)

Depomed's expert, Dr. Appel, opines that these examples are significant due to the plateaus in the dissolution profile during the later stages of drug release in sustained or extended release dosage forms:

> Many sustained or extended release dosage forms show a plateau in the dissolution profile during the later stages of release. This plateau is expected with certain types of dosage forms that release via mechanisms that provide a smaller driving force for drug release at later portions of the release profile, e.g. diffusional hydrophilic matrix tablets and osmotic tablets.
>
> The rate of drug release from [] hydrophilic matrix tablets that release via a diffusional mechanism is proportional to the difference between the concentration of drug in solution inside the dosage form and outside the dosage form. During much of the release profile the drug concentration in the dosage form is saturated (at the solubility of the drug in the specific environment of the tablet). At the later stages of the release profile, the drug is depleted so that concentration of drug inside the tablet falls below the saturated solubility. This results in a decrease in the driving force for release and a lower release rate. This effect continues until there is effectively no driving force for drug release and can result in a significant plateau for drug release, a phenomenon referred to as "tailing." This is nicely illustrated in Figure 1 of the '475 Patent that shows tailing occurring in the release profile between 70-90% release. Therefore, in light of the disclosure in the patents, it is appropriate to say that "substantially all" of the drug is released once 80% of the drug has been released.

(Dkt. 132-17 at 17.)

Depomed, citing the two FDA Guidance documents, argues that the extrinsic evidence supports its constructions. Depomed argues that these documents explain that in *in vitro*/*in vivo* dissolution testing, the endpoint of testing should occur where at least 80% of the drug from the drug product is dissolved. Depomed's expert, Dr. Appel,

opines that based on these documents, in conjunction with the disclosures in the patents-in-suit, the POSA would understand the "substantially all of said drug" terms to mean "at least 80% of the drug." (See dkt. 132-17 at 18-19.) Dr. Appel explains that:

> These FDA Guidance documents were written by and for those skilled in the art, and therefore reflect the understanding of a person of skill in the art of pharmaceutical dosage forms in 1997. A person of skill in the art in the pharmaceutical industry would look for such FDA publications for guidance in the meanings and scopes of relevant subject matters, over other sources of information, since the FDA ultimately decides whether to approve a new drug product. It is imperative that the formulator understand the FDA's guidances regarding appropriate testing of dosage forms in development to ensure the dosage for developed meets FDA standards.

(Id.)

The Court has considered the parties' respective arguments and the relevant evidence. The Court concludes that the claim terms including the phrase "substantially all of said drug" are not indefinite. Accordingly, the Court will adopt the constructions proposed by Depomed.

"[A] claim must 'inform those skilled in the art about the scope of the invention with reasonable certainty' to meet the definiteness requirement of 35 U.S.C. § 112, ¶ 2." Liberty Ammunition, Inc. v. United States, 835 F.3d 1388, 1396 (Fed. Cir. 2016) (quoting Nautilus, 134 S. Ct. at 2129). Yet, we must recognize that "absolute precision is unattainable" when drafting patent claims. Nautilus, 134 S. Ct. at 2129. If absolute precision were required, terms like "substantially" or "about" would have no place in patent law. The term "substantially" is in fact common in general usage and patent claim drafting, and its use alone is not enough to make a claim indefinite. See, e.g., Aventis

Pharm. Inc. v. Amino Chemicals Ltd., 715 F.3d 1363, 1377 (Fed. Cir. 2013) (construing "substantially" as "largely but not wholly"). It is clear to this Court that "a patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement." Sonix Tech. Co. v. Publ'ns Int'l, Ltd., No. 2016-1449, 2017 WL 56321, at *5 (Fed. Cir. Jan. 5, 2017) (quoting Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1384 (Fed. Cir. 2005)).

We agree with Judge Breyer that "[c]ommon sense indicates that 'substantially all' of a substance refers to some percentage approaching 100% of the relevant material—in other words, some measure just short of it." Ivax, 2006 WL 3782829, at *4. While the top boundary may be capable of a definition using merely words, the bottom boundary here is what is difficult to define. We agree that the intrinsic record fails to provide a strong indication as to the boundary of the term. See id. at *5. The term is not defined in the claims or the specification. The statement in the Summary section referring to a "majority of the drug" being released is less than helpful, as it could be interpreted to mean greater than 50% and less than or equal to 100%. See U.S. Philips Corp. v. Iwasaki Elec. Co., 505 F.3d 1371, 1379 (Fed. Cir. 2007). The multiple examples showing at least 80% of the drug being released within ten hours are only somewhat persuasive. Two-thirds of the final drug release percentage measurements are above 80%, however there is variance within those measurements. (See dkt. 133 at 20.) We, like the other district courts before us, must turn to the extrinsic evidence to determine the meaning of this claim.

The FDA Guidances are most helpful in our mission to determine if these claim terms are indefinite. These documents were written to provide "recommendations to pharmaceutical sponsors of new drug applications (NDAs), abbreviated new drug applications (ANDAs), and abbreviated antibiotic drug applications (AADAs)" related to the composition and manufacture of "a modified release solid oral dosage form during the postapproval period," (dkt. 132-15 at 6), and "pharmaceutical sponsors who intended to develop documentation in support of an in vitro/in vivo correlation (IVIVC) for an oral extended release (ER) drug product for submission in a [NDA], [ANDA], or [AADA]." (Dkt. 132-16 at 5.) In other words, they were written for the POSA.

The data collected in the patents-in-suit appears consistent with the FDA Guidances, that look to the "at least 80%" drug release as a reasonable marker of how much drug is released in the "last stage of dissolution." As discussed above, the FDA Guidances explain that "[t]he last time point should be the time point where at least 80% of drug has dissolved" or "[i]f the maximum amount dissolved is less than 80%, the last time point should be the time when the plateau of the dissolution profile has been reached." (Dkt. 132-16 at 21, see also dkt. 132-15 at 11 ("Adequate sampling should be performed, for example, at 1, 2, and 4 hours and every two hours thereafter until either 80% of the drug from the drug product is released or an asymptote is reached.".) The literature directed to the POSA places considerable emphasis on the 80% mark, as the appropriate end point for testing dissolution of a drug. The Court finds these documents to be highly persuasive evidence that the claim term "substantially all," as read in light of the specification delineating the patent and prosecution history, informs, with reasonable

certainty, those skilled in the art about the scope of the invention. Accordingly, we conclude that the substantially all claim terms are not indefinite. We agree with and give appropriate deference to Judge Breyer and Judge Pisano's reliance on the FDA Dissolution Guidance and will adopt Depomed's proposed construction.

Accordingly, the Court construes the "substantially all" claim terms as follows: "releases substantially all of said drug within about eight hours after such immersion" means "at least 80% of the drug has been released after eight hours of immersion in gastric fluid;" "releases substantially all of said drug after such immersion" means "at least 80% of the drug has been released after immersion in gastric fluid;" "releases substantially all of said drug within about ten hours after such immersion" means "at least 80% of the drug has been released after teen hours of immersion in gastric fluid;" "until substantially all of said drug is released" means "at least 80% of the drug has been released;" and "while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic environment" means "at least 80% of the drug has been released after immersion in gastric fluid."

6. Claim terms concerning poly(ethylene oxide) molecular weights

With respect to these claim terms, Depomed contends that no construction is necessary, and that the plain and ordinary meaning should apply because the POSA would understand the plain and ordinary meaning of "about" to mean "approximately." Depomed's expert, Dr. Appel, explains that polymer molecular weight is typically measured by means of gel permeation chromatography (GPC). (See dkt. 132-17 at 24-25.) According to Dr. Appel, "GPC is known by persons skilled in the art to have

accuracy and precision of 5-10% when calculating a molecular weight average, meaning any value within 5-10% could represent the same underlying molecular weight distribution." (Id. at 4.) Dr. Appel cautions against assigning a fixed range to the word "about" because the accuracy of polymer molecular weight measurements is highly dependent on polymer type, sample preparation, measurement equipment, analytical technique, and data analysis. (Id. at 25.) However, when considering the range offered by Purdue, Dr. Appel does state that "a more appropriate range would be 20% variation, making said range 3,600,000 to 12,000,000 and 4,000,000 to 9,600,000, respectively." (Id.) Depomed acknowledges that these ranges would overlap, but asserts that they still claim different ranges, and, therefore, cover different inventions. (See dkt. 161 at 46-47.)

Purdue employs a significant figure analysis to arrive at its proposed constructions for these terms. (See dkt. 133 at 31-32.) Purdue's expert, Dr. Atwood, explains that

> When reporting numerical values, it is important to properly identify which numbers are significant—i.e., which numbers are intended to be precise—as opposed to which numbers are merely placeholders to indicate the scale of the number. The rule recognized by those skilled in the art is that numbers that are within the range of uncertainty are rounded. Thus, the last reported significant figure can have a maximum uncertainty of ± 1.

(Dkt. 133-1 at 25-26.) Based on the significant figure analysis, Purdue states that

> The number "4,500,000" has at least two significant figures, the "4" and the "5." (The zeros may or may not be significant, depending on context.) Thus, "about 4,500,000" should not extend below 4,400,000. Given that the patent contrasts 4,500,000 with 5,000,000, the first zero in "5,000,000" is also significant, so "about 5,000,000" should not extend below 4,900,000."

(Dkt. 133 at 32.) However, Dr. Atwood opines that the POSA would have understood the maximum uncertainty of the claimed poly(ethylene oxide) molecular weights to be 5%. (Dkt. 133-1 at 26.) He states that an uncertainty of 6% or greater would result in a scenario with overlapping ranges between the bounds of the claim terms. (See id.) Thus, Purdue adopts 5% as the uncertainty and concludes that "about 4,500,000 to about 10,000,000" means 4,275,000 to 10,500,000 and "about 5,000,000 to about 8,000,000" means "4,750,000 to 8,400,000." (See dkt. 133 at 32.)

Finally, Purdue argues that a determination that these claim terms have their plain, ordinary meaning would be inadequate to resolve the dispute between the parties, and requests that this Court provide some definition of the metes and bounds of these claim terms.

The Court has considered the parties' respective arguments and the relevant evidence. The Court construes the claim term "about 4,500,000 to about 10,000,000" to mean "3,600,000 to 12,000,000", and construes the claim term "about 5,000,000 to about 8,000,000" to mean "4,000,000 to 9,600,000."

For the claim terms "about 4,500,000 to about 10,000,000" and "about 5,000,000 to about 8,000,000," there is little, if any, intrinsic evidence sufficient to guide the Court's determination. The written description does not provide an explicit definition for the term "about" in the context of these claims. The ranges of molecular weights of preferred poly(ethylene oxide) polymers and more preferred poly(ethylene oxide) polymers are merely reported in the written description without any further elaboration.

See '475 Pat., col. 8, ll. 31-40. In addition, neither party references any portion of the prosecution history that may guide our analysis.

Both parties rely exclusively on the testimony of their respective experts. We find the testimony of Dr. Appel to be more persuasive on this point. As discussed above, Dr. Appel's testimony explains that the accuracy of a molecular weight measurement is highly dependent on multiple factors, and that the word "about," in that context, must refer to a range wider than the known accuracy of the measurement technique, which she opines is 20%. The significant digit analysis put forth by Purdue is too imprecise. Purdue and its expert fail to provide any explanation as to why certain digits, in the context of a molecular weight range of a polymer, must be significant. In fact, Purdue states that "[t]he zeros may or may not be significant, depending on context." (Dkt. 133 at 32.) Purdue's arguments in no way consider the realities of molecular weight measurement. Moreover, Purdue argues that "about 4,500,000" should not extend below 4,400,000, yet advocates for a variance of 5% which results in a figure (4,275,000) that *does* extend below 4,400,000. Purdue's arguments related to the significant figure analysis fail to persuade us.

The Court also does not find Purdue's argument related to claim differentiation to be persuasive. The Court recognizes that the claim terms, as construed, overlap in part. However, they still claim different ranges of molecular weights and, therefore, are different. See In re Rembrandt Techs., LP, 496 F. App'x 36, 45-46 (Fed. Cir. 2012).

The Court appreciates Purdue's concern that given the parties' dispute, declining to construe this term or construing it to have its plain and ordinary meaning would be

inadequate. As a result, the Court will adopt the range set forth by Depomed in the alternative. This construction accounts for the realities of molecular weight measurement, and will provide a definition for the metes and bounds of the claims.

Accordingly, the Court construes the claim term "about 4,500,000 to about 10,000,000" to mean "3,600,000 to 12,000,000", and construes the claim term "about 5,000,000 to about 8,000,000" to mean "4,000,000 to 9,600,000."

III. CONCLUSION

For the reasons stated above, the Court hereby construes the claim terms as follows:

the claim term "gastric fluid," as used in the specified claims of the '475 and '280 Patents, means "both the fluid in the stomach and simulated or artificial fluids recognized by those skilled in the art as a suitable model for the fluid of the human stomach;"

the claim term "remains substantially intact," as used in the specified claims of the '475 and '280 Patents, means "a polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles;"

the claim term "until all of said drug is released," as used in the specified claims of the '475 Patent, means "[until] 100% of the drug has been released;"

the claim term "said polymeric matrix being one the swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode," as used in claim 1 of the '475 Patent, means "the dosage form, which comprises a polymeric matrix, increases in size due to the ingress of water, such that

when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours;"

the claim term "said polymeric matrix being one that swells upon imbibition of gastric fluid to a size large enough to promote retention in the stomach during said fed mode," as used in claim 43 of the '475 Patent, means "the dosage form, which comprises a polymeric matrix, increases in size due to the ingress of gastric fluid, such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours;"

the claim term "when swollen in a dimensionally unrestricted manner as a result of imbibition of water," as used in claim 1 of the '280 Patent, is construed to have its plain, ordinary meaning;

the claim term "when swollen in a dimensionally unrestricted manner as a result of imbibition of gastric fluid," as used in claim 43 of the '280 Patent, is construed to have its plain, ordinary meaning;

the claim term "is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode," as used in the specified claims of the '280 Patent, means "such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours;"

the claim term "releases substantially all of said drug within about eight hours after such immersion," as used in the specified claims of the '475 and '280 Patents, means "at least 80% of the drug has been released after eight hours of immersion in gastric fluid;"

the claim term "releases substantially all of said drug after such immersion," as used in claim 1 of the '280 Patent, means "at least 80% of the drug has been released after immersion in gastric fluid;"

the claim term "releases substantially all of said drug within about ten hours after such immersion," as used in the specified claims of the '475 and '280 Patents, means "at least 80% of the drug has been released after ten hours of immersion in gastric fluid;"

the claim term "until substantially all of said drug is released," as used in claim 1 of the '280 Patent, means "at least 80% of the drug has been released;"

the claim term "while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic environment," as used in the specified claims of the '475 and '280 Patents, means "at least 80% of the drug has been released after immersion in gastric fluid;"

the claim term "about 4,500,000 to about 10,000,000," as used in the specified claims of the '475 and '280 Patents, means "3,600,000 to 12,000,000;" and

the claim term "about 5,000,000 to about 8,000,000," as used in the specified claims of the '475 and '280 Patents, means "4,000,000 to 9,600,000."

The Court will issue an appropriate order.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: April 6, 2017